REMARKS

Status of Claims:

Claims 1-11 were pending in the application. Claims 10 and 11 were withdrawn pursuant to a restriction requirement. Claim 4 is hereby cancelled. The cancellation and/or withdrawal of claims is without prejudice to, or disclaimer of, the subject matter contained therein. The Applicant reserves the right to further prosecute the subject matter of the present application, including any cancelled or withdrawn claims in subsequent division, continuation, and/or continuation-in-part application(s). Claims 1-3 and 5-9 are now pending. Each of the pending claims defines an invention that is novel and unobvious over the cited art. Favorable reconsideration of this case is respectfully requested.

Request for Rejoinder.

The Examiner's restriction cited 37 CFR 1.475(b) "an international or national stage application...will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specifically adapted for the manufacture of said product."

Claim 10 recites the product, (S)-(-)-amlodipine-hemi-L-tartrate-1/4-DMSO-solvate. The elected process, recited in claims 1-9, is specifically adapted to produce the product claimed in claim 10 and, therefore, meets the criteria of 37 CFR 1.475(b). The Applicants respectfully request the rejoinder of claim 10.

Disclosure Supporting the Instant Amendment:

Paragraph 0024 of the specification is amended to recite the ¼-DMSO solvate. Support for this recitation was present in the original disclosure at, for example, paragraph 0022.

The specification is amended to include an abstract of the disclosure. Support is found in paragraph 0001 of the original disclosure.

Rejections Under 35 U.S.C. § 112, 2nd Paragraph:

Claims 1-3 were rejected under 35 U.S.C. § 112, 2nd Paragraph, as being indefinite for reciting the trade name "amlodipine."

In response, Claim 1 is hereby amended to recite the chemical name of amlodipine.

Rejection Under 35 U.S.C. § 102(b):

Claims 1-9 were rejected under 35 U.S.C. § 102(b) or (e) as being anticipated by Joshi (2003/0176706).

Claim 1 recites a method for the production of S-(-)-amlodipine, known chemically as: 3-ethyl 5-methyl-(-) 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methylpyridine-3,5-dicarboxylate. According to the present invention, the method proceeds through the formation of a crystalline intermediate, the (S)-(-)-amlodipine-hemi-L-tartrate-**1/4**-DMSO-solvate, the entity claimed as such in Claim 10. Joshi discloses a method for producing S-(-)-amlodipine. However, Joshi proceeds through the formation of a completely different crystal form than is disclosed and claimed in the present invention.

Joshi discloses S(-)amlodipine-hemi L(+)-tartarate **mono** DMSO solvate. The unit crystal of the present invention contains one DMSO molecule per four amlodipine molecules. In contrast, the unit crystal of Joshi contains amlodipine and DMSO in a 1:1 molar ratio. Joshi does not disclose the intermediate product claimed by the present invention; neither does Joshi describe methods for its synthesis, nor does Joshi describe a use for it. Therefore, Joshi does not anticipate the present invention.

Rejections Under 35 U.S.C. § 103(a):

Claims 1-9 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Joshi.

The *prima facie* case of obviousness must at minimum recite each claimed element of the invention. The Examiner cites the teachings of Joshi at sections [0009] and [0014] for the prior art reaction.

Step 1: reacting (R,S)-amlodipine with L-(+)-tartaric acid in dimethyl sulfoxide (DMSO);

Step 2: filtering the resultant precipitate and precipitating S(-)amlodipine-hemi L(+)-tartarate monohydrate with methylene chloride; and

Step 3: basification to form S(-)amlodipine.

The Examiner's exposition concedes that Joshi's method does not proceed through the formation of an (S)-(-)-amlodipine-hemi-L-tartrate-**1/4**-DMSO-solvate intermediate. In contrast to Joshi, the present invention has such an intermediate:

Step i: reacting (R,S)-amlodipine with L-(+)-tartaric acid in DMSO;

Step ii: filtering the precipitate of step (i);

Step iii: adding methylene chloride and precipitating (S)-(-)-amlodipine-hemi-L-tartrate-1/4-DMSO-solvate;

Step iv (optional): adding alcohol to the ¼-DMSO-solvate to form the monohydrate; and

Step v: basifying either, the ¼-DMSO-solvate of Step iii, or the monohydrate of Step iv, to form S(-)amlodipine.

Whether or not the optional monohydrate is produced, the present invention proceeds through a ¼-DMSO-solvate intermediate which is neither disclosed, nor claimed by Joshi.

Because Joshi neither discloses, nor claims the intermediate product of the present invention, Joshi neither anticipates, nor renders obvious the present invention.

Conclusion:

In view of the above, consideration and allowance are respectfully solicited.

Accordingly, it is respectfully requested that the foregoing amendments be entered, that the application as so amended receive an examination on the merits, and that the claims as now presented receive an early allowance.

In the event the Examiner believes an interview might serve to advance the

prosecution of this application in any way, the undersigned attorney is available at the telephone number noted below.

The Commissioner is hereby authorized to charge any fees and to credit any overpayments that may be required by this paper under 37 C.F.R. §§ 1.16 and 1.17 to Deposit Account No. 02-2135.

Respectfully submitted,

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By: John A. Evans Reg. No. 34,627

John A. Evans
Registration No. 44,100

Rothwell, Figg, Ernst & Manbeck PC
1425 K Street, N.W., Suite 800
Washington, D.C. 20005
(202) 783-6040 (voice)
(202) 783-6031 (fax)